

**REMARKS**

**STATUS OF THE CLAIMS**

Claims 2, 4-10, 24-43, 49-60, 63-66, and 68-75 are pending as in the paper filed February 17, 2005. Applicants thank the Examiner for careful attention to the claims and note that claim 41 was mistakenly listed as not pending in the Remarks section of the last-filed paper (February 17, 2005). However, the listing of the claims in the last-filed paper properly identified claim 41 as pending. Thus, claim 41 is in fact pending.

**PRIORITY**

Applicants note that the Office has acknowledged that Applicants are entitled to the benefit of the filing date of 60/152,195 (filed September 1, 1999). Applicants disagree with the Office's position that provisional application 60/114,495 (filed December 31, 1998) does not provide adequate written description for the pending claims inasmuch as the claimed subject matter is an obvious extension of what is described in co-owned 60/114,495.

**REJECTIONS WITHDRAWN**

Applicants note with appreciation that all the previous rejections under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, enablement and written description, have been withdrawn.

Applicants also acknowledge withdrawal of the rejections under 35 U.S.C. § 102(f) and the obviousness-type double patenting rejection over U.S. Serial No. 09/899,575.

**35 U.S.C. § 102(E)**

Claims 2, 4, 7, 24, 25, 27, 28 and 41-43 were rejected as allegedly anticipated by U.S. Patent No. 5,990,091 (hereinafter "Tartaglia"). (Office Action, pages 3-4). In support of this rejection, it was stated:

The sequence taught by Tartaglia anticipates a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO:3 and 4 of the instant application because the claims encompass a nucleotide sequence encoding an amino acid sequence having 70% sequence identity to the amino acid sequence encoded by SEQ ID NO:3 and 4 of the instant application. Tartaglia teaches that recombinant vCP1433 and vCP1452 has an insert that encodes a polypeptide sequence having 81.4% identity to SEQ ID NO:3 and 78.8% identity to SEQ ID NO:4.

Because the rejection is factually and legally unsustainable, Applicants traverse the rejection and supporting remarks.

Factually, Applicants remind the Office that the claims are directed to polynucleotides, not to polypeptides. There cannot be sequence identity as between polypeptides and polynucleotides because one cannot compare apples (nucleotides) and oranges (amino acids). Therefore, the Examiner's statement that "the polypeptide encoded by the insert of vCP1433 and vCP1452 exhibits X% identity to SEQ ID NOs:3 and 4" is wrong.

Even assuming that the Examiner meant to indicate that the polypeptide encoded by the insert of vCP1433 and vCP1452 exhibits X% identity to a polypeptide that could possibly be encoded by a sequence exhibiting 90% identity SEQ ID NOs:3 or 4, the rejection remains legally untenable. In order to be an anticipatory reference, the single reference cited by the Office must disclose each and every element of the claims. *Hybritech v. Monoclonal Antibodies*, 231 USPQ 81 (Fed. Cir. 1986). Moreover, the single source must disclose all of the claimed elements arranged as in the claims. *See, e.g., Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989). Simply put, the law requires identity as between the prior art disclosure and the invention. *See, e.g., Kalman v. Kimberly-Clark Corp.* 218 USPQ 781 (Fed. Cir. 1983), *cert. denied*, 484 US 1007 (1988).

Here, the pending claims are directed to polynucleotides that necessarily exclude wild-type HIV Gag-encoding sequences (*i.e.*, wild-type polynucleotides do not exhibit 90% identity to the claimed sequences). It is improper for the Examiner to read a limitation into the claims (70% sequence identity at the polypeptide level) and base an anticipation rejection on an unclaimed element. When properly read for what it discloses about polynucleotides, it is clear that Tartaglia discloses only wild-type HIV Gag-encoding sequences. Such polynucleotides do not fall within the scope of the claims and, indeed, are specifically **excluded** by the language requiring that the claimed polynucleotide exhibit at least 90% sequence identity to the polynucleotides of SEQ ID NOs:3 or 4.

Simply put, any sequence identity that **may** exist as between polypeptides encoded by the claimed sequences and polypeptides encoded by Tartaglia's inserts is utterly irrelevant to patentability of the pending claims. The relevant question is whether Tartaglia discloses a polynucleotide exhibiting 90% identity to SEQ ID NOs:3 or 4, as claimed. Tartaglia clearly contains no such disclosure and, accordingly, this reference cannot anticipate the pending claims.

### 35 U.S.C. § 102(F)

Claims 2, 4, 5, 24, 25, 41, 42, 68 and 74 were again rejected under 35 U.S.C. § 102(f) as allegedly not invented by Applicant in view of claim 72 from co-pending application 09/967,464 and over claim 72 of "U.S. Publication '453." The Examiner provides the full citation of U.S. Publication '453 on page 23 of the Office Action (U.S. Publication 20030138453). The two cited

references, 09/967,464 and the '453 publication, are actually one and the same. Thus, this is a single rejection under 35 U.S.C. § 102(f) alleging that 09/967,464 (which published as the '453 publication) includes inventors which are not named on the instant patent application.

Applicants again traverse this rejection on the grounds that 09/967,464, as a later-filed application, cannot show invention by another. Not only are the claims in 09/967,464 directed to different subject matter (and therefore, names different inventors), the 09/967,464 is not a proper reference against the pending case. As set forth by the Court of Customs and Patent Appeals in *In re Katz*, 215 USPQ 14 (CCPA 1982), a reference can be used to establish a prima facie 102(f) rejection only if it was published before applicant's filing date. The pending application was filed in December 1999 while the cited reference was not published until 2003 (and, indeed, was not filed in 2001). Thus, nothing regarding a prior invention can be assumed from a subsequent publication or filing. Accordingly, withdrawal of this rejection is in order.

### 35 U.S.C. § 103

Pending claims 2, 4, 5, 7-10, 24-43, 49-60, 63-66, and 68, 70, 72 and 74 were variously rejected under 35 U.S.C. § 103 as allegedly obvious over Tartaglia in view of various secondary references. (Office Action, pages 7-21). Claims 2, 4, 8 and 9 were rejected as allegedly obvious over Tartaglia in view of Rovinski. Claims 2, 4, and 8-10 were rejected as allegedly obvious over Tartaglia in view of Rovinski and further in view of Rubenstein and Johnson. Claims 2 and 24-25 were rejected as allegedly obvious over Tartaglia in view of U.S. Patent No. 6,489,542 (hereinafter "Corbin"). Claims 2 and 24-26 were rejected as allegedly unpatentable over Tartaglia in view of Corbin and further in view of either Sikic or Dubensky. Claims 2, 27-32 and 35-40 were rejected as allegedly unpatentable over Tartaglia in view of the ATCC catalog. Claims 2, 27 and 33 were rejected as allegedly unpatentable over Tartaglia in view of Helting. Claims 2, 27 and 34 were rejected as allegedly unpatentable over Tartaglia in view of Adams. Claims 2, 4, 41, 49, 50, 51, 52, 54, 58, 59 and 60 were rejected as allegedly unpatentable over Tartaglia in view of Tobin. Claims 2, 4, 41, 49, 50 and 52-53 were rejected as allegedly unpatentable over Tartaglia in view of Tobin and further in view of Marrow. Claims 2, 4, 41, 49, 50, 52, and 55 were rejected as allegedly unpatentable over Tartaglia in view of Tobin and further in view of Kafri. Claims 2, 4, 41, 49, 56-57 were rejected as allegedly unpatentable over Tartaglia in view of Robin and further in view of Lai. Claims 2, 4, 41, 49 and 63-66 were rejected as allegedly unpatentable over Tartaglia in view of Tobin and further in view of Moore.

For the reasons noted above, Tartaglia does not describe, demonstrate or suggest polynucleotides as claimed. Thus, there is no combination of Tartaglia with any of the secondary references that can support an obviousness rejection.

Indeed, it is well settled that claims to polynucleotide sequences are not obvious in view of a disclosure of protein sequences encoded by the polynucleotides. *See, e.g., In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993). Furthermore, it is also axiomatic that an obviousness rejection of polynucleotide claims cannot be based on the combination of a reference teaching a protein encoded by the polynucleotides and a generalized reference teaching how to isolate or manipulate DNA. *In re Deuel* 34 USPQ2d 1210 (Fed. Cir. 1995).

Accordingly, Tartaglia's disclosure of wild-type polynucleotide sequences cannot render obvious claims directed to synthetic polynucleotide sequences that exclude such wild-type sequences, regardless of the polypeptide encoded by these polynucleotides. Thus, the claims are novel and non-obvious over Tartaglia, either alone or in light of any of the secondary references (including generalized knowledge regarding manipulation of polynucleotides). Withdrawal of the rejections under section 103 is, therefore, in order.

#### **OBVIOUSNESS-TYPE DOUBLE PATENTING**

Claims 2, 4, 5, 24, 41, 42, 43 and 68 and 74 were again provisionally rejected under the judicially created doctrine of obviousness type double patenting as allegedly obvious over claims 7, 26, 28, 31-50 and 72 of co-pending and commonly owned application 09/967,464 (which is also US Patent Publication 20030138453), either alone or in view of Tartaglia and other references.

Again, there is nothing in Tartaglia that describes or suggests the polynucleotides as claimed and, as noted above, 09/967,464 is directed to a different invention and is not available as a reference against the pending application. Thus, the rejections based on the combined teachings of 09/967,464 and Tartaglia cannot be sustained.

**CONCLUSION**

In view of the foregoing amendments, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §1.16, §1.17, and §1.21, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648, referencing Atty. Docket No. 2302-1631.20.

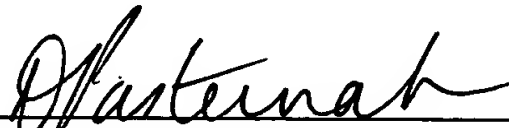
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Respectfully submitted,

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